REMARKS

Status of Application

Claims 31, 33 and 34 are pending in this application. Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g) (old ground). They also stand rejected as "unpatentable under *res judicata*" (new ground). No claim amendments have been made and no new matter has been added to this application.

Examiner's Reply

Rejections

35 U.S.C. § 102(g)- Anticipation

Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g) as being anticipated by either one of Sugano et al., U.S. Patent 5,514,567 or Sugano et al., U.S. Patent 5,326,859. The Examiner states that each of the Sugano patents recites a DNA that encodes the same amino acid sequence as is recited in claim 34. The Examiner also states that each of the Sugano patents recites a DNA that is embraced by claim 31, parts (a) and (b). Finally, the Examiner states that each of the Sugano patents recites methods of using IFN-β in the treatment of human cancers and tumors that are embraced by claims 31 and 34. Applicants traverse.

Neither Sugano patent is 35 U.S.C. § 102(g) art to pending claims 31 or 34. As a matter of law, the Sugano patents cannot form the basis of a 102(g) rejection. Section 102(g) provides a single basis for rejection and unpatentability: the invention was made in this country by another inventor before the patentee's invention.

The Sugano patents are not evidence of an invention made in this country. MPEP § 2138. Indeed, applicant Fiers has an earlier priority date than any United States filing date to which the Sugano patents may be entitled. For an *ex parte* 102(g) rejection, there must be a

reduction to practice in the United States before applicant's invention. The Examiner has pointed to no such reduction to practice. The Examiner's reliance on the Federal Circuit's decision is misplaced. That decision does not hold that Sugano made any actual reduction to practice in the United States. The Examiner contends that the Sugano patents disclose the same amount of information relevant to the methods claimed in the pending application. Whether or not that is true, it is irrelevant. The earliest United States application that led to the Sugano patents was filed on October 27, 1980. Fiers' claims are entitled to at least the June 6, 1980 filing date of his UK patent application 80.18701. Accordingly, the Sugano patents are not 102(g) art to the pending claims. Fiers requests, therefore, that the Examiner reconsider this rejection and allow the pending claims.

Res Judicata

Claims 31 and 34 newly stand rejected as being unpatentable under *res judicata*. The Examiner contends that applicant is estopped from receiving a patent directed to the pending claims because of the judgment in *Fiers* v. *Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993).

There are two reasons why this "estoppel" rejection should be withdrawn.

First, during the *Fiers* v. *Revel* v. *Sugano* Interference (Interference 101,096), Fiers specifically moved to add a count directed to a method for treating, cancers and tumors. These methods were characterized by an IFN-β_1, produced in a microbial host cell transformed with a DNA encoding that IFN-β_1. *See*, Fiers July 20, 1984 Motion re Proposed Count 9 ("Exhibit A", copy attached) at p. 3. Sugano opposed that Motion. He argued that Fiers had failed to show that the proposed count was patentable to and supported by the Sugano application in interference. *See*, Sugano September 10, 1984 Opposition ("Exhibit B", copy

attached). In his Reply, Fiers specifically argued that, in Fiers' view, the Sugano priority applications did not support the proposed count and that Sugano had not demonstrated to the contrary. Fiers further pointed out that he was making the motion to preclude Sugano from trying to claim the claimed methods of treatment in the future. *See*, Fiers November 5, 1984 Reply ("Exhibit C", copy attached), at pp. 3-4.

Primary Examiner Smith dismissed the Fiers motion as moot:

> Fiers requests that Revel et al. [and Sugano] be required to demonstrate the patentability of proposed Counts 3-9 to themselves as well as support for the proposal counts in their U.S. applications, or otherwise be estopped from asserting a right to the subject matter of those counts in subsequent *ex parte* or interference proceedings. The request is moot until subsequent *ex parte* or interference proceedings occur. Accordingly, it is dismissed as moot.

See, January 9, 1985 Decision, ("Exhibit D", copy attached) at p. 5.

Having moved, albeit unsuccessfully, to have the priority of the subject matter of the now pending method of treating claims contested in the interference, Fiers cannot be estopped by the priority decision on other subject matter (DNA) in the interference. *See, e.g.*, 37 C.F.R. § 41.127. Particularly, this is true here, where the reason that the Primary Examiner dismissed Fiers' motion was that it was moot until subsequent ex parte prosecution. That is the very situation that Fiers now finds himself in the context of the pending claims.

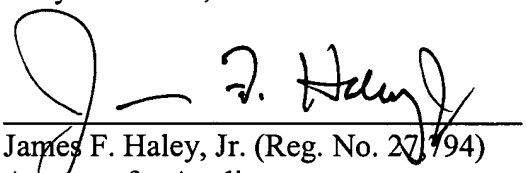
Second, Fiers understands and believes that other parties are now, and perhaps, for a long time, have been taking steps to provoke interferences with or otherwise to contest the cited Sugano patents in the context of the production and use of IFN-β (collectively "Third Party Requests"). To the extent those Third Party Requests have merit and are granted, it would be unfair and unjust to preclude Fiers from being part of those proceedings on the basis of a patentability decision in the pending Fiers application that would, of necessity, be directly contrary to the action taken in the context of the Third Party Requests.

For both of the above reasons, Fiers requests that the new ground of rejection – estoppel – be withdrawn or at least suspended until the Third Party Requests are fully resolved.

Conclusion

For all of the reasons set forth herein, Fiers respectfully requests that the Examiner reconsider the rejection of claims 31 and 34 and allow the pending claims.

Respectfully submitted,



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